Application No. 10/633,484 Attorney Docket No.: 05033.0003.00US00

In the Claims:

1-32. (Cancelled)

33. (Previously Presented) A method for detecting cervical dysplasia, cervical cancer or <u>high</u> grade cervical intraepithelial neoplasia in human cervical body samples comprising:

preparing a sample solution by solubilizing a human cervical sample in a lysis buffer; determining the level of at least one relevant marker characteristic for the presence of eervical dysplasia, cervical cancer or cervical intraepithelial neoplasia in human p16^{INK4a} having SEQ ID NO: 13 within the sample solution and comparing with the level of the p16^{INK4a} of a normal human cervical sample;

determining the level of at least one normalization marker characteristic for the presence of ectocervical or endocervical cells within the sample solution, wherein said normalization marker is selected from the group consisting of gamma-Catenin, SEQ ID NO: 1; Ep-Cam, SEQ ID NO: 2; E-Cadherin, SEQ ID NO: 3; alpha-1 Catenin, SEQ ID NO: 4; alpha-2 Catenin, SEQ ID NO: 5; beta-Catenin, SEQ ID NO: 6; Involucrin, SEQ ID NO: 7; CK8, SEQ ID NO: 8; CK18, SEQ ID NO: 9; CK10, SEQ ID NO: 10; CK13, SEQ ID NO: 11; and p120, SEQ ID NO: 12;

determining the adequacy of the sample by comparing the levels of the normalization markers detected determined within the sample solution with threshold levels of the normalization markers determined from an adequate and predefined amount of ectocervical cells or endocervical cells; and

detecting cervical dysplasia, cervical cancer or cervical intraepithelial neoplasia based on the levels of the relevant markers and the adequacy of the sample, whereby when the sample is adequate level of the normalization marker within the sample solution is higher than the threshold level, the positive an elevated level of the relevant markers p16^{INK4a} within the sample solution is indicative of cervical dysplasia, cervical cancer or high grade cervical intraepithelial neoplasia.

34-35. (Cancelled)

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- 36. (Original) The method according to Claim 33, wherein said method is used in early detection or primary screening tests of cervical lesions.
- 37. (Original) The method according to Claim 33, wherein said human cervical body sample is a swab, a secretion, an aspirate, a lavage, a cell, a tissue, a biopsy or a body fluid.
- 38. (Cancelled)
- 39. (Currently Amended) The method according to Claim 33, wherein said normalization marker <u>indicating indicates</u> the presence of endocervical cells <u>and</u> is selected from the group consisting of SEQ ID NOs: 2, 8, and 9.
- 40. (Currently Amended) The method according to Claim 33, wherein said normalization marker <u>indicating indicates</u> the presence of <u>endocervical ectocervical and</u> is selected from the group consisting of SEQ ID NOs: 1, 3-7, 11, and 12.
- 41-53. (Cancelled)
- 54. (Previously Presented) The method according to Claim 39, wherein said normalization marker is SEQ ID NO: 2.
- 55. (Previously Presented) The method according to Claim 40, wherein said normalization marker is SEQ ID NO: 1.
- 56. (New) A method for detecting cervical dysplasia, cervical cancer or high grade cervical intraepithelial neoplasia in human cervical body samples comprising:

preparing a sample solution by solubilizing a human cervical sample in a lysis buffer; determining the level of p16^{INK4a} having SEQ ID NO: 13 within the sample solution and comparing with the level of the p16^{INK4a} of a normal human cervical sample;

determining the presence or absence of a detectable level of at least one normalization marker characteristic for the presence of ectocervical or endocervical cells within the sample solution, wherein said normalization marker is selected from the group consisting of gamma-Catenin, SEQ ID NO: 1; Ep-Cam, SEQ ID NO: 2; E-Cadherin, SEQ ID NO: 3; alpha-1 Catenin,

SEQ ID NO: 4; alpha-2 Catenin, SEQ ID NO: 5; beta-Catenin, SEQ ID NO: 6; Involucrin, SEQ ID NO: 7; CK8, SEQ ID NO: 8; CK18, SEQ ID NO: 9; CK10, SEQ ID NO: 10; CK13, SEQ ID NO: 11; and p120, SEQ ID NO: 12;

whereby when the level of the at least one normalization marker is detectable, an elevated level of p16^{INK4a} within the sample solution is indicative of cervical dysplasia, cervical cancer or high grade cervical intraepithelial neoplasia.

- 57. (New) The method according to Claim 56, wherein said method is used in early detection or primary screening tests of cervical lesions.
- 58. (New) The method according to Claim 56, wherein said human cervical body sample is a swab, a secretion, an aspirate, a lavage, a cell, a tissue, a biopsy or a body fluid.
- 59. (New) The method according to Claim 56, wherein said normalization marker indicates the presence of endocervical cells and is selected from the group consisting of SEQ ID NOs: 2, 8, and 9.
- 60. (New) The method according to Claim 56, wherein said normalization marker indicates the presence of ectocervical cells and is selected from the group consisting of SEQ ID NOs: 1, 3-7, 11, and 12.
- 61. (New) The method according to Claim 59, wherein said normalization marker is SEQ ID NO: 2.
- 62. (New) The method according to Claim 60, wherein said normalization marker is SEQ ID NO: 1.